K014163

510(k) Summary

JAN 2 2 2002

1.0 Date Prepared

January 14, 2002

2.0 Submitter (Contact)

Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name:	Stimulation / Dissection Instruments (Tradenames have not been finalized at this time)
Common Name(s):	Nerve Stimulator / Locator
Classification Name(s):	Surgical Nerve Stimulator / Locator

4.0 Device Classification

Classification Name: Surgical Nerve Stimulator / Locator and accessories

Procode 77ETN	Class II	21 CFR § 874.1820
Procode Various	Class I	21 CFR § 874.4420
Procode Various	Class I	21 CFR § 878.4800

5.0 Device Description

The designs of the Stimulus - Dissection Instruments are similar to existing stainless steel manual surgical instruments. The instruments consist of scissors, forceps, retractors, and hooks with biocompatible electrical insulation applied to selected portions, and proximal connectors provided to attach the instruments to a monopolar stimulator. The distal surfaces of the instruments are non-insulated stainless steel to provide for mechanical, manually actuated dissection / resection, and tissue stimulation. The Stimulus - Dissection Instruments are a protected pin design and meet the requirements of IEC 60601-1:1988 /A1:1991 /A2:1995 Clause 56.3(c) per 21 CFR 898.12. Accessories include monopolar cables available in lengths up to 3 M.

6.0 Indications for Use

The Stimulus-Dissection Instruments are indicated for tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

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510(k) Summary *(continued)*

7.0 Substantial Equivalence

The design, technology, features, function, and intended use of the intraoperative neurological stimulation feature of the Stimulus-Dissection Instrument is substantially equivalent to Medtronic Xomed Monopolar Stimulator Probe originally described in K992869.

The design, technology, features, function, and intended use of the mechanical dissection feature is substantially equivalent to Class I exempt manual surgical instruments such as those described in 21 CFR § 874.4420 and 21 CFR § 878.4800.

Characteristic	**Stimulus - Dissection Instruments**	**Ball-Tip Monopolar Stimulating Probe [K992869]**
Indications For Use	Tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.	To stimulate cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.
Stainless steel construction	Yes	Yes
Electrical insulation	Electrical insulation on all surfaces not intended to provide electrical contact with the patient	Electrical insulation on all surfaces not intended to provide electrical contact with the patient
Distal stainless steel patient contact surface	Yes	Yes
Proximal stimulator connector	Yes	Yes
IEC 60601-1 Protected Pin design	Yes	Yes
Biocompatible	Yes	Yes
Steam autoclavable	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2002

Medtronic Xomed, Inc.
c/o Martin D. Sargent
6743 Southpoint Dr. North
Jacksonville, FL 32216

Re: K014165
Trade/Device Name: Stimulation/Dissection Instruments
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: December 18, 2002
Received: December 19, 2002

Dear Mr. Sargent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K014165

Device Name: Stimulus - Dissection Instruments

Indications for Use:

The Stimulus - Dissection Instruments are indicated for tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Karen Baker for

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

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